

# Determining When Pre-License / Pre-Approval Inspections are Necessary

SOPP 8410

Appendix 1

## Waiver Memorandum

**Date:** [date]

**From:** [name], HFM-[], CMC Reviewer  
[name], HFM-[], BLA Committee Chair

**To:** BLA File – STN [STN #]

**Subject:** Recommendation to waive a pre-license inspection

**Sponsor:** [Applicant], U.S. License # []

**Contract:** [contract manufacturer, if applicable]

**Product:** [name, including trade name]

**Indication:** [product's primary indication for use]

**Through:** [name, branch chief of CMC reviewer], HFM-[]  
[name, branch chief/supervisor of committee chair], HFM-[]

## Clearance Routing

---

[name] CONCUR DO NOT CONCUR DATE  
Director, Division of Manufacturing and Product Quality, HFM-670  
Office of Compliance and Biologics Quality, CBER

---

[name] CONCUR DO NOT CONCUR DATE  
Director, Division of [product division], HFM-[]  
[product office]

cc: [name, director of applications division], HFM-[]  
[name], Branch Chief, Program Inspection Branch, HFM-604

**Summary:** [brief summary of memo]

**Brief History**

[Describe the nature of the submission, such as original application or supplement to describe manufacturing change.]

**Facility Information**

[Describe the operations performed at the site for which waiver of inspection is proposed.]

**Supporting Information**

[This section should include information to support the recommendation to waive the preapproval or pre-license inspection. The information should address the points in the SOPP, and should refer to previous inspection information, where applicable. The memo should include a statement that the criteria in the SOPP were evaluated. Where necessary, attachments may be included.]

**Waiver Recommendation:**

[brief summary of basis for recommendation and conclusion]

Signed:

[name, CMC reviewer], HFM-[] \_\_\_\_\_ DATE \_\_\_\_\_

[name, committee chair], HFM-[] \_\_\_\_\_ DATE \_\_\_\_\_